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Jarrow FORMULAS, INC™

Superior Nutrition and Formulation℠

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October 5, 1999

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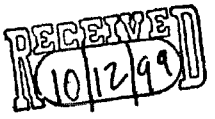
ATTN: Structure & Functions Claim Filing — BioSil™

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. S.W.
Washington, DC 20204



Dear Sir or Madam:

While checking our files, we uncovered a BioSil™ Structure/Function submission to your agency that may not have been sent. The employee responsible for these submissions is no longer with our company and, therefore, we can not corroborate if it was ever submitted. In light of new text used for BioSil™, we are submitting a revised structure/function disclosure.

Pursuant to Section 403(r)(6) of the Federal food, Drug and Cosmetic Act and Section of 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

(1) Name and address of distributor:

Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035

(2) Text of the statement(s):

Clinically Proven Liquid Silicon Concentrate: BioSil. Biologically Active Silicon as Stabilized Orthosilicic Acid.

- Essential for Bone Formation
- Supports Joint Function
- Essential for Collagen Production
- Strengthen and beautifies hair, skin and nails

97S-0162

BioSil's active silicon is an essential partner of calcium for bones, glucosamine for joints, and antioxidants for healthier arteries and cardiovascular function. The Importance of Silicon - Silicon is a trace mineral required for the formation of healthy connective tissue, bone, skin, hair and nails. Silicon is essential for collagen formation, healthy arteries and regulates calcium deposition in bones. Dietary sources of silicon (as found in food, horsetail [silica] and colloidal gel products) are very poorly absorbed because of their insoluble, polymerized forms. For absorption to occur, dietary silicon must be first converted to Orthosilicic Acid (monomeric silicic acid), the bioavailable form found in BioSil.

BioSil Insert: Biologically Active BioSil - The Revolutionary Advantage of Stabilized Orthosilicic Acid.

BioSil contains silicon in the form of stabilized Orthosilicic acid: the only biologically active form of silicon. Unlike horsetail or colloidal gel, which must convert in the stomach to Orthosilicic Acid, BioSil absorbs immediately and directly through the stomach wall. BioSil is clearly the best choice:

1) High Potency -- Introducing BioSil into the stomach increases the Orthosilicic Acid concentration by a factor of 20,000. Normally the solubility of Orthosilicic Acid is limited:

LET 4504

Orthosilicic Acid is present in water and body fluids at an average concentration of 1 mcg of net elemental silicon per ml (one part per million or 0.0001%). However, due to its unique stabilization formula BioSil contains 20,000 fold more silicon per ml, i.e., 2% silicon as Orthosilicic Acid.

2) Maximum Absorption -- BioSil is a high absorption silicon product. BioSil contains a high concentration of biologically active silicon: stabilized Orthosilicic Acid. Orthosilicic Acid is the only silicon compound that absorbs directly through the stomach wall and the gastro-intestinal tract into the bloodstream. BioSil's superior absorbability has been scientifically proven. When calves had their total dietary silicon intake increased by 5% in the form of Biosil, silicon blood levels increased 70% compared to control animals without supplementation. This study also demonstrated a 12% higher collagen concentration in the skin of animals supplemented with Biosil compared to control animals. This increase in collagen formation has important implications for bones and joints since collagen is the major fibrous protein in this tissue. While the preliminary results from one single-dose clinical study indicate that silicon from horsetail absorbs slightly better than colloidal gel, BioSil absorbs 2.5x better than horsetail or colloidal silica gel.

All Tissue Requires Silicon for Strength and Elasticity: **A) Bones -- Silicon is essential for collagen formation and complexing calcium into bone tissue (bone mineralization). Eisinger and Clairet (1993) showed that silicon supplementation can increase the bone density of the femur (the bone from the hip to the knee). In a recent supplementation study of calves with BioSil, it was shown that the serum calcium concentration correlated positively with serum silicon concentration (Calomme and Vanden Berghe 1997). This research also established that low serum concentrations of silicon were associated with lower serum calcium concentrations. On the other hand, silicon deficiency caused both skull and long bone abnormalities in chicks and rats. Silicon deficient animals were also found to have decreased concentrations of collagen, calcium, magnesium, phosphorous and glycosaminoglycan in bone and cartilage tissue (Carlisle 1970).**

b) Joints -- Silicon is essential for activating the enzymes that form and maintain articular cartilage in joints, as well as ensuring the integrity of ligaments. Nutritional silicon deficiency in animals caused the development of small, poorly formed joints and decrease articular cartilage content (Carlisle 1976).

C) Aorta and Other Arterial Tissue -- Silicon is essential for the strength and integrity of the tunica intima, the inner lining of arterial tissue. The tunica intima consists of elastin, which like collagen is silicon dependent. Diseased arteries are severely deficient in silicon.

E) Nails -- The predominant minerals in nails are calcium, silicon and sulfur. A sign that silicon may be systemically deficient is nails that are brittle or soft.

F) Skin -- Silicon from BioSil was shown to increase the collagen concentration in the dermis of the skin up to 12.5% (Calomme and Vanden Berghe 1997). Silicon is crucial for activating the hydroxylation enzymes for cross-linking collagen, which improves the strength and elasticity of this fibrous protein.

D) Hair -- Silicon helps hair grow thicker and stronger.

G) Aluminum -- Silicon also protects against aluminum toxicity (Birchall et al., 1989). Rats fed a diet low in calcium and silicon, but high in aluminum, accumulated high amounts of aluminum in the brain (Carlisle and Curran 1987). Silicon supplementation inhibits the increase in concentration of aluminum in the brain by lowering the bioavailability of aluminum in food and beverages.

H) Ageing and Decline of Silicon Levels in Tissue -- As we age, our ability to metabolize dietary silicon into Orthosilicic Acid declines. Silicon supplementation often becomes essential for maintaining the strength and integrity of virtually every important tissue in the body: from bones, joints, skin, capillaries, arteries, and even brain tissue.

(3) Name of the dietary ingredient if not provided in the text of the statement:

Orthosilicic acid (see above)

(4) Name of the dietary supplement

BioSil™

(5) *The following disclaimer appears on the label*: These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients. A compendium of relative published research substantiating the above statement(s) is on file at the corporate office.

Respectfully submitted,

Siddharth Shastri

Director of Product Development